Appl. No.: 10/007,257
Amdt. dated 01/18/2005
Reply to Office action of November 18, 2004

Amendments to the Claims:

1. (Currently Amended) Water soluble particles of less than 50 μm comprising a coprecipitant core with a dehydrated biological macromolecule coated thereon;

wherein the coprecipitant core consists of one of the following ~~is selected from the group consisting of~~

inorganic salts,

sugars, ~~polysaccharides,~~ polyols, and derivatives thereof with a molecular weight of less than 10,000 Da;

amino-acids;

acid-base buffers;

zwitterionic compounds;

organic salts;

compounds containing multiple basic groups;

compounds containing multiple acidic groups;

bile salts; and,

water soluble dyes.

2. (Currently Amended) Water soluble particles according to claim 1 wherein the coprecipitant core is ~~partially or~~ substantially crystalline.

3. (Original) Water soluble particles according to claim 1 wherein the dehydrated biological macromolecule is selected from peptides, polypeptides, proteins and nucleic acid.

4. (Original) Water soluble particles according to claim 1 having a diameter less than 10 μm.

5. (Canceled)

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6. (Currently Amended) A method of preparing water soluble particles comprising a coprecipitant core with a dehydrated biological macromolecule coated thereon comprising the steps of:

a) preparing an aqueous solution comprising a coprecipitant and a biological macromolecule wherein the coprecipitant core consists of one of the following ~~is selected from the group consisting~~ of inorganic salts; sugars, ~~carbohydrates,~~ polyols, and derivatives thereof with a molecular weight less than 10,000 Da; amino-acids; acid-base buffers; zwitterionic compounds; organic salts; compounds containing multiple basic groups; compounds containing multiple acidic groups; bile salts; and, water soluble dyes;

b) rapidly admixing the biological macromolecule/coprecipitant solution with an excess of a water miscible organic solvent such that the coprecipitant and bioactive molecule immediately coprecipitate from solution forming said particles; and

c) isolating said particles from the organic solvent.

7. (Previously presented) The method according to claim 6 wherein the aqueous solution comprising the coprecipitant and the biological macromolecule is prepared by dissolving the coprecipitant in an aqueous solution comprising the biological macromolecule.

8. (Previously Presented) The method according to claim 6 wherein the biological macromolecule/coprecipitant solution is added to the water miscible organic solvent.

9. (Original) The method according to claim 6 wherein the coprecipitant biological macromolecule molar ratio is greater than 50.

10. (Canceled)

11. (Original) The method according to claim 6 wherein the organic solvent is selected from methanol, ethanol, propanol, acetonitrile, tetrahydrofuran and acetone.

12. (Original) Particles obtainable by the process according to claim 6.

13. (Previously presented) A pharmaceutical formulation comprising particles according to claims 1 or 12 and a suitable carrier therefor.

14. (Original) A medical device comprising particles according to claims 1 or 12 associated therewith.

15. (Original) Particles according to claims 1 or 12 for use in therapy.

16. (Original) A biocatalyst preparation comprising particles according to claims 1 or 12 associated therewith.

17. (Original) A cleansing agent comprising enzyme coated particles according to claims 1 or 12.

18. (Original) A protective or antifouling agent comprising particles according to claims 1 or 12 in association with paint, varnish, coatings or films.

19. (Original) Films, polymers, inks, coatings, electrodes and optical materials for diagnostic kits or biosensor applications, comprising particles according to claims 1 or 12.

20. (Original) A method for studying molecular recognition, molecular binding, molecular imprinting or inhibitor binding in non-aqueous media, comprising using particles according to claims 1 or 12.

21. (Original) A method for studying macromolecule structure and/or organisation by scanning probe microscopy, comprising using particles according to claims 1 or 12.

22. (Previously Presented) A method of isolating a biological macromolecule from an aqueous solution, comprising the steps of:

a) preparing an aqueous solution comprising a mixture of a coprecipitant and biological macromolecule to be isolated; and

b) admixing the biological macromolecule/ coprecipitant solution with an excess of a water miscible organic solvent such that the coprecipitant and biological macromolecule immediately coprecipitate from solution to form water soluble particles of less than 50 μm and having a coprecipitant core with a dehydrated biological macromolecule coated thereon, with rapid simultaneous dehydration of the biological macromolecule.

23. (Previously presented) Water soluble particles of less than 50 μm comprising a coprecipitant core with a dehydrated biological macromolecule coated thereon obtainable by:

a) preparing an aqueous solution comprising a coprecipitant and biological macromolecule; and

b) admixing the biological macromolecule/ coprecipitant solution with an excess of a water miscible organic solvent such that the coprecipitant and biological macromolecule immediately coprecipitate from solution forming said particles; and

c) isolating said particles from the organic solvent.

24. (Currently Amended) Biological macromolecule coated micro-crystals comprising a coprecipitant core with a dehydrated biological macromolecule coated thereon, wherein the coprecipitant core consists of one of the following: ~~and is selected from the group consisting of~~

inorganic salts,

sugars, ~~polysaccharides,~~ polyols, and derivatives thereof;

amino acids;

acid-base buffers;

zwitterionic compounds;

organic salts;

compounds containing multiple basic groups;

compounds containing multiple acidic groups;

bile salts; and,

water soluble dyes.

25. (Currently Amended) A pharmaceutical formulation comprising biological macromolecule coated micro-crystals comprising a coprecipitant core with a dehydrated pharmaceutically active biological macromolecule coated thereon, wherein the copreicipitant core consists of one of the following: ~~and is selected from the group consisting of~~

inorganic salts,

sugars, ~~polysaccharides,~~ polyols, and derivatives thereof with a molecular weight less than 10,000 Da;

amino-acids;

acid-base buffers;

zwitterionic compounds;

organic salts;

compounds containing multiple basic groups;

compounds containing multiple acidic groups;

bile salts; and,

water soluble dyes;

and a suitable carrier therefor.

26. (Previously presented) An inhalable pharmaceutical formulation comprising biological macromolecule coated micro-crystals comprising a coprecipitant core with a dehydrated pharmaceutically active biological macromolecule coated thereon.

27. (Previously presented) Water soluble particles of less than 50 μm comprising a coprecipitant partially, substantially or crystalline core with a dehydrated biological macromolecule coated thereon.

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28. (Previously Presented) Water soluble particles comprising a coprecipitant core with a dehydrated bioligcal macromolecule coated thereon, wherein the coprecipitant is selected from ionic salts, amino acids, zwitterionic compounds, organic salts, sugars and polysaccharides of a molecular weight of less than 1,000 Da.

29. (Cancelled)

30. (Previously presented) Water soluble particles comprising a coprecipitant core coated with a dehydrated biological macromolecule wherein the coprecipitant has a melting point at atmospheric pressure greater than 95°C.

31. (Previously presented) A liquid suspension comprising water soluble particles comprising a coprecipitant core coated with a biological macromolecule.

32. (Previously presented) A method of purifying a biological macromolecule from additives or impurities comprising:

a) dissolving a coprecipitant in an aqueous solution comprising the biological macromolecule and additive or impurity wherein the coprecipitant is selected from the group consisting of inorganic salts; sugars, carbohydrates, polyols, and derivatives thereof with a molecular weight less than 10,000 Da; amino-acids; acid-base buffers; zwitterionic compounds; organic salts; compounds containing multiple basic groups; compounds containing multiple acidic groups; bile salts; and, water soluble dyes;

b) admixing the biological macromolecule/ coprecipitant solution with an excess of a water miscible organic solvent or solvents, in which the additive or impurity is soluble, such that the coprecipitant and biological macromolecule immediately coprecipitate from solution forming a biological macromolecule coated particle comprising a core of coprecipitant;

c) rinsing said particles with fresh water-miscible organic solvent; and

d) isolating said particles.

33. (Previously presented) Water soluble particles according to claim 1 wherein the coprecipitant is trehalose.

34. (Previously presented Currently Amended) Water soluble particles according to claim 1 wherein the coprecipitant is an amino acid selected from the group consisting of glycine and arginine.

35. (Previously presented) The method according to claim 11 wherein the coprecipitant is trehalose.

36. (Previously presented) The pharmaceutical formulation according to claim 25 wherein the coprecipitant is trehalose.

37. (Previously presented) The pharmaceutical formulation according to claim 25 wherein the coprecipitant is an amino acid selected from the group consisting of glycine and arginine.

38. (Previously presented) The pharmaceutical formulation according to claim 28 wherein the coprecipitant is trehalose.

39. (Previously presented) The pharmaceutical formulation according to claim 28 wherein the coprecipitant is an amino acid selected from the group consisting of glycine and arginine.

40. (Previously Presented) Water soluble particles according to claim 1 wherein said coprecipitant core is a non-polymeric core.

41. (Previously Presented) The method according to claim 6 wherein said coprecipitant core is a non-polymeric core.